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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09 835,072	04 13 2001	David R. Goodlett	P-IS 4584	3882

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/22/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835.072

Applicant(s)

GOODLETT ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 20, 22 and 30-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 3 Sheets 6) ☐ Other

DETAILED ACTION*APPLICANTS' ELECTION*

Applicants' election with traverse of Group II (claims 19-29, drawn to a method of determining an amino acid sequence of a polypeptide by differentially labeling two or more polypeptide mixtures), Species B (terminal amino acid), and Species E (an amino acid without post-translational modifications) in Paper No. 6, filed 04 September 2002, is acknowledged. Applicants traversal is on the grounds that the search and examination of the entire application would not pose a serious burden to the Examiner since a thorough search of the elected claims of Group II would include art relevant to the claims of Groups I, III, and IV. Applicants' argument is found persuasive to the extent of the rejoinder of Groups I and II, since the claims of Group II depend from Group I. However, with regard to the rejoining of all Groups (particularly Groups II, III, and IV) applicants are directed to Paper No. 5, mailed 26 July 2002, which provides mass spectra practice with differing set(s) of requirements in the determination of an amino acid sequence of a polypeptide thus distinctly separating the inventions into respective groups and establishing the basis of an undue search burden. It is acknowledged that the methods of Groups I-IV are classified within the same class and subclass, however, classification does not exclude such processes from restriction since it has been shown that each invention contains divergent subject matter and are distinctly different processes. Applicants' argument that the election of species requirement is improper due to the multi-level election requirement first requiring an election of the location of the amino acid residue and subsequent election of a particular post-translational modification state of an amino acid is found unpersuasive. It was established in Paper No. 5, mailed 26 July 2002, that each species adds a feature to the mass spectra methods

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with different and distinct functions (i.e. specific location(s) of where the differential label marks an amino acid residue and amino acid modification processing) in which each would require a separate and burdensome search. Claims 5, 7, 14, 20, 22, and 30-55 are withdrawn from examination as not directed to the elected invention and/or subject matter.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-4, 6, 8-13, 15-19, 21, and 23-29.

SEQUENCE COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). This application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 due to the sequence as in the specification on page 5, line 8; page 55, lines 14 and 16; and page 66, lines 9-16, and no submission of the following items. Therefore, applicants are required to submit the following:

1. As a separate part of the disclosure on paper copy or compact disk copy, a "Sequence Listing" as 37 C.F.R. § 1.821(c).
2. A copy of the "Sequence Listing" in computer readable form as required by 37 C.F.R. § 1.821 (e).
3. A statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. § 1.821 (f) and 37 C.F.R. § 1.821 (g).
4. Each sequence in the specification is required to have a SEQ ID NO. therewith.

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Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance requirement. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this office action.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 13 (line2) and 28 (line 2) recite the phrase "low resolution" which implies some criteria of selection. Applicants can resolve this issue by particularly pointing out what the criteria is regarding "low resolution". Clarification of the metes and bounds, via clearer claim wording, is required.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claims 1-4, 6, 8-13, 15-19, 21, and 23-29 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Gygi et al. (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, *Nature Biotechnology*, October 1999, Volume 17, pages 994-999).

Gygi et al. describes an approach for the accurate quantification and concurrent identification of the individual proteins within complex mixtures utilizing isotope-coded affinity tags and tandem mass spectrometry (Abstract; instant claims 13, 19, and 28 [refer to the above 112 2nd Paragraph Rejection regarding "low resolution"])). The isotope-coded affinity tags (ICAT) consist of three functional elements: a specific chemical reactivity, an isotopically coded linker (i.e. hydrogen and deuterium), and an affinity tag (page 994, Column 2, lines 7-9 and Figure 1; instant claims 8, 9, 23, and 24). The ICAT strategy for quantifying differential protein is described as the following: 1) protein mixtures are isotopically treated with light and heavy ICAT reagents (instant claims 11 and 26); 2) the protein mixtures are combined, proteolyzed to peptides, and ICAT labeled peptides are isolated utilizing the biotin tag (instant claims 10 and 25); 3) these peptides are separated by microcapillary high-performance liquid chromatography (instant claim 29) and differences are measured by mass spectrometry and displayed graphically ; 4) followed by fragmentation and automatically recording sequence information (instant claims 17 and 18); and 5) protein is identified by computer searching the sequence information against protein databases (instant claims 12 and 27)(depicted in Figure 2; page 996, Column 2, lines 1-2; and page 999, Column 1, lines 1-58 of the Experimental Protocol section). The authors illustrate the ICAT sequence identification of a peptide wherein fragment ions in the mass spectra represent sequence information recorded from both the N and C terminus of the peptide as in

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instant claims 1-4, 6, 15, 16, and 21 (Figure 4). Thus, Gygi et al. clearly anticipates the claimed invention.

OBJECTION OF DISCLOSURE

The disclosure is objected to because of the following informalities:

The specification is objected to because of a typographical/spelling error: "plypeptide" should be replaced with "polypeptide" (page 5, line 22).

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *October 21, 2002*

Examiner Initials: *CSM*


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600